

Important Information. Please read carefully.

# Bena® Expectorant Clears Chesty Cough

# Composition

# Pharmacodynamic

Diphenhydramine Hydrochloride is a sedating antihistamine that helps to reduce nasal secretions. Ammonium Chloride is used as an expectorant in productive cough. It increases the volume of secretions in the respiratory tract thereby facilitating their removal by ciliary action and coughing.

## **Pharmacokinetics**

Diphenhydramine hydrochloride is well absorbed from the gastrointestinal tract. Peak plasma concentrations are achieved about 1 to 4 hours after oral doses. Diphenhydramine is widely distributed throughout the body including the CNS. Diphenhydramine is highly bound to plasma proteins. Metabolism is extensive. Diphenhydramine is excreted mainly in the urine as metabolites; little is excreted as unchanged drug. The elimination half-life has been reported to range from 2.4 to 9.3 hours.

Ammonium chloride is absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver, the anion thus liberated into the blood and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine; this is followed by transient diuresis.

# Indications

Bena is indicated for the relief of chest congestion and coughs with thick phlegm. It clears nasal passages, liquefies and loosens stubborn phlegm and soothes tiresome coughing.

# **Dosage and Administration**

For oral use only.

Unless otherwise prescribed by the physician:

Adult and children over 12 years:
 5 to 10 ml every 4 to 6 hours
 (not to exceed 60ml in 24 hours);

# · Children 6 to 12 years:

2.5 to 5 ml every 4 to 6 hours (not to exceed 30 ml in 24 hours);

# · Children 2 to 5 years:

2.5 ml every 4 to 6 hours (not to exceed 20 ml in 24 hours).

Take medication with a full glass of water. Do not exceed the stated dose.

## Side Effects

Antihistaminic side effects include sedation, dizziness, tinnitus, lassitude, incoordination, fatigue, blurred vision, diplopia, euphoria, nervousness, insomnia and tremors. Incidences of gastrointestinal side effects are low.

Large doses of ammonium chloride may cause nausea, thirst, headache and progressive drowsiness leading to profound acidosis and hypokalaemia. Excessive sodium salt may cause hypernatraemia. These effects are unlikely to occur with therapeutic dose of the preparation due to its low content of ammonium chloride.

# Contraindications

In patients with known hypersensitivity to antihistamines.

# Warning and Precautions

This medicine may cause drowsiness. If affected, do not drive motor vehicles or operate machinery. Avoid taking alcoholic drinks or other drugs that may produce drowsiness.

Bena should be used with caution in patients with hepatic or renal diseases. Safety of this preparation in pregnancy has not been established and should be carefully assessed before use.

#### Warning

When used for treatment of cough and cold: Not to be used in children less than 2 years of age. To be used with caution and doctor's/ pharmacist's advice in children 2 to 6 years of age.

## **Drug Interactions**

Alcohol, tranquilizers, sedative-hypnotics and CNS depressants – increase CNS depression. MAO inhibitors – increases anticholinergic effects.

# **Pregnancy and Lactation**

#### Pregnancy

Reproduction studies in rats and rabbits given up to 5 times the human dose have shown no evidence of impaired fertility or harm to the fetus; use during pregnancy only if clearly needed.

#### Lactation

Contraindicated for use in nursing mothers due to the increased risk of antihistaminic side effects in newborns and infants.

# Symptoms and treatment of overdosage

Antihistamine overdosage may produce a mixture of excitatory and depressive effects on the central nervous system. Marked cerebal irritation, resulting in jerking of muscles and possible convulsions, may be followed by stupor.

There is no specific antidote for antihistamine poisoning. Symptomatic and supportive treatment may be employed. In severe overdosage, the stomach should be emptied by aspiration and lavage. Convulsions may be controlled with diazepam given intravenously.

## Shelf-life

The expiry date is indicated on the packaging.

# Presentation

Brown pleasantly flavoured expectorant cough mixture in packs of 90ml and 120ml.

#### Storage

Store in a cool place below 30°C.

# KEEP OUT OF REACH OF CHILDREN JAUHI DARI KANAK-KANAK

For further information, please consult your pharmacist or physician.

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Manufacturer and Product Registration Holder

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